## REMARKS

Applicants acknowledge receipt of an Office Action dated November 15, 2005. In this response applicants have amended claim 1 and added claims 29-31. These changes are amply supported by the original specification, e.g., on page 4 at line 32, on page 5 at lines 10 and 11, and on page 18 at lines 22 *ff.* Accordingly, no new matter has been introduced.

Upon entry of the present response, claims 1-31 will be pending. Reconsideration of the application, thus revised, is respectfully requested in view of the foregoing amendments and these remarks.

**Rejections Under 35 U.S.C. § 112, Second Paragraph**

On page 2 of the Office Action, Examiner Davis has rejected claim 28 for indefiniteness alleged in relation to applicants' use of "respectively." Without acquiescing to the examiner's stated rationale, applicants have chosen to advance prosecution by revising claim 28 to address her specific concern. The essential meaning of the claim is unchanged.

**Rejections Under 35 U.S.C. § 103**

In keeping with prior actions, Examiner Davis has advanced a number of obviousness rejections, each premised, in principal part, on the combined teachings of U.S. patent No. 6,146,667 (Sing) and U.S. patent No. 5,098,721 (Kosikowski). To be quite clear, applicants traverse each and every rejection of record because a sustainable case of obviousness, as to claim 1 and its dependents, cannot stand on a foundation of Sing plus Kosikowski, regardless of what secondary references are brought into the analysis. Applicants also reiterate their previously stated grounds for distinguishing particular claims over certain permutations of Sing/Kosikowski teachings with those of other cited references.

The examiner acknowledges that the Sing/Kosikowski combination does "not teach ***the method*** wherein the subsets [of concentrated stock inoculum material] are provided to different factories and/or plants," as claim 1 presently prescribes (office action, *e.g.*, at page 5, last paragraph; emphasis added). Nevertheless, the examiner maintains that

> ... where the actual steps take place [does] not patentably distinguish *the method* from the prior art, since practicing *the methods* at different

> locations would not materially change *the culture method*. Absent evidence that practicing *the method* in "different locations" would materially change *the method steps* of those in the prior art, the claims are rendered obvious.

Action at page 23, second paragraph (emphasis added).

In these quotations, applicants have highlighted each mention of "method" in order to underscore a critical error in the examiner's reasoning, which is to confound the claimed method "as a whole," per Section 103, with different method steps identified in one or another of the cited references. As claimed, applicant's methodology requires, *inter alia*, the "providing [of] a subset to a different propagation factory or plant" [claim 1, subparagraph (b)] and "inoculating said cultivation medium at the different ... factory or plant" [subparagraph (c)]. Accordingly, the examiner cannot equate applicants' "method" with some subset of steps, such as "concentrating," "dividing" and "inoculating" at a single site, and then adjudge obviousness from the perspective of whether carrying out this "method" at different locations "materially changes" the "culture method."

Section 103 requires that the examiner gauge obviousness, from the vantage point of the skilled artisan at the time of original filing, with respect to "the differences between the subject matter sought to be patented and the prior art." 35 USC § 103(a) (1995). It necessarily follows that the examiner cannot derogate the acknowledged difference discussed above, affecting both steps (b) and (c), simply because on-site manipulations ("the culture method") may be the same from site to site. Put another way, it is legal error twice over to shift to the evidentiary burden to applicants (there is no *prima facie* case) to prove that an integral, recited aspect of the claimed invention is "material" to some other aspect (contravenes "as a whole" mandate of Section 103).

For these reasons alone, the pending obviousness rejections lack merit and should be withdrawn. Still, applicants would hasten to add that the "different locations" aspect of the claimed invention in fact is identified with a significant or material improvement, achieved by use of the invention in a trans-regional or international operation. Implementing the method as claimed allows such an operation, which may have propagation plants located all around the world, to manufacture starter cultures with a consistent quality, such that all plants produce essentially the same, high quality product.

This qualitative improvement, which the application discusses in detail under heading "1.4 Conclusion" (original specification at page 17 *et seq.*), was not realized before the present invention was implemented, possibly due to factors of cultural diversity among locally employed personnel, differences in equipment, variation as to the sorts of contamination in the different factories, etc. In other words, higher quality and consistency are achieved, in accordance with the claimed invention, by sending the stock inoculum material made in a single, state-of-the-art plant to the network of plants, thereby avoiding the local inoculation steps that were endemic to the prior art. Consequently, the claimed methodology makes it possible to control the quality at the single plant and only release stock inoculum material that has a sufficiently high quality. Pursuant to the invention, local staff at distant plants then need only pour the stock inoculum material into a fermentor containing the cultivating medium, in a conventionally aseptic manner.

Thus characterized, the claimed invention is properly viewed as empowering the establishment of a far-flung, even global network of plants, all of which can produce starter cultures of a quality and consistency not presaged by the art of record. To the contrary, in conventional practice a quality assurance step is performed when a starter culture production is initiated, *i.e.*, when the primary inoculation material (usually in frozen or freeze-dried form) is propagated in the first step, and not just before the stock inoculum material is added to the main fermentor. By applying a quality testing step to the stock inoculum material, as when using one for the subsets of the present invention for quality testing, and releasing (and shipping) the approved batches of stock inoculum material to one or more different plants, one assures higher consistency and quality with the claimed method.

Against not only an acknowledged difference but also a resultant advantage, as discussed, separating the claimed invention from the prior art, the examiner can assert, as to Kosikowski, only that it "could be further implied that such subsets could be shipped to other locations, ... since the subsets are used as starter cultures" (action at page 24, second sentence). Respectfully, whether Kosikowski's subsets *could* be shipped to other locations is no evidence at all that the reference would have suggested such a step to the person of ordinary skill. The implication drawn by the examiner is informed by hindsight alone and, hence, is wholly improper under Section 103.

Applicants also must point out the factual error involved in analogizing, as the examiner has done, between the presently recited "subsets" and the aliquots divided out by Kosikowski. More specifically, the examiner has stated that

> ...Kosikowski teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures can be used as bulk starters (or starter cultures) and that Kosikowski additionally teaches the mother culture can be concentrated for storage (col. 1) prior to division and inoculation.

Initially, applicants note that a "mother culture" or primary inoculation material (see specification at page 14, line 10) is not synonymous with the "stock inoculum material" obtained in accordance with the claimed method. Further, the "mother culture" of Kosikowski is divided into subsets not to be stored but rather to be transferred into multiple growth mediums, the best of which is selected for making the bulk starter immediately, without storage, in contrast with the presently claimed invention but much in keeping with Kosikowski's guidance on making multiple growth mediums on a daily basis (see below).

Secondly, Kosikowski actually does not teach that "mother cultures .... are divided into subsets...wherein the cultures can be used as bulk starters," as the examiner contends. Rather, the reference teaches in column 1 that:

> "*the mother or bulk starter can be stored in several forms*" (line 34);
>
> "*the mother starter is synonymous with certified seed*" (line 29); and
>
> "*the mother culture is a small volume of inoculated growth medium, for example cultured milk or whey which is periodically transferred, usually daily, into a plurality of growth medium containers...*" (line 24).

Thus, Kosikowski teaches that the mother starter but not "the best resulting cultures" can be stored. By the same token, it is incorrect for the examiner to urge that Kosikowski teaches that (mother) cultures can be used as bulk starters, and likewise incorrect that the mother culture of Kosikowski is divided into subsets, which are thereby used as a bulk starter.

Both legal and factual errors thus militate strongly in favor of the examiner's withdrawing the pending obviousness rejections, each of which relies on Kosikowski as well as Sing. Applicants would only add that the evidence of record comports with the distinctions and advantages discussed above in relation to the claimed invention.

For instance, the Børge Kringelum declaration of record shows that, when the claimed method is carried out with a non-mixed (single) culture, the percentage of approved batches is increased, relative to the conventional process. Further, the declaration evidence shows that, when the claimed method is carried out with a mixed culture such as R-603, the percentage of approved batches is not increased.

In her action mailed June 28, 2004, the examiner discounted the Børge Kringelum declaration on several technical grounds, such as an alleged inconsistency between numbers of batches run. Yet, even if one presumes, arguendo, that parameters other than consistent quality may influence the number of approved batches, the declaration still would show that using the claimed methodology yielded a higher percentage of batches of high quality than was achieved previously.

This result indicates that, with all other parameters unchanged, the inoculum has a higher quality when the claimed method is employed. The same conclusion pertains with respect to additional data, obtained worldwide by the assignee upon general implementation of the claimed method:

**Data Collected Globally from 01 Oct 2001 to 01 March 2006**

| Bacterial culture | Produced per claimed invention | Discarded batches | Discarded (%) |
|---|---|---|---|
| FDVS R-603 | 223 | 3 | 1.3 |
| FDVS R-604 | 629 | 6 | 1.0 |
| PFD LA-1 | 230 | 1 | 0.4 |

As these additional data show, the assignee was empowered by the claimed methodology to produce bacterial cultures with almost no incidence of discarded batches, a result that the skilled artisan would have regarded as wholly surprising in view of Sing, Kosikowski, and the other cited publications.

## CONCLUSION

In view of the foregoing, applicants respectfully submit that all of the pending claims are in condition for allowance. An early notice to this effect is earnestly solicited. If there are any questions or additional issues regarding the application, Examiner Davis is invited to contact the undersigned at the number below.

Respectfully submitted,

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